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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,113	10/22/2003	Boris Y. Shekunov	PER-14651	5325
7609	7590	07/30/2004		
RANKIN, HILL, PORTER & CLARK, LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405				
			EXAMINER	
			DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER
			1723	
DATE MAILED: 07/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/691,113

Applicant(s)

SHEKUNOV ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 20 is rejected under 35 U.S.C. 102(b or e) as being anticipated by Holl et al patent 6,471,392.

Holl et al disclose vessel 30 or 32, rotor 42, annular mixing zone 44, inlets 14 (column 13, lines 28-34), means for collecting 52 (column 3, lines 57-58) and collecting of particulates means (column 7, lines 32-38 and 58-61, see "precipitation").

Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Zhou et al document PGPUBS US2004/0115123.

Zhou et al disclose stator 3, rotor 4 defining mixing zone therebetween, inlets 7,8 and 9, and means for collecting particles 10 (paragraph 39).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al PGPUBS Document US2004/0091546, published 05/13/2004.

Johnson et al disclose providing a 1<sup>st</sup> solution with dissolved solute (page 3, paragraph 34, providing anti-solvent that may be supercritical carbon dioxide (page 6, paragraph 58 and, if necessary, page 7, paragraph 63), flowing the fluids through a chamber or vessel containing a rotor to mix (page 4, paragraph 41) and mixing in the

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annular space between wall of vessel and rotor and collecting precipitated nanoparticles (paragraphs 41 and 58).

With regard to claims 3,7-11 and 20, plural solvents may be added through additional multiple inlets and ports (page 4, last 2 lines of para 37 and page 5, para 45).

With regard to claim 2, see para 41 concerning streams forced to vessel walls by "centripetal" forces.

With regard to claims 4-6, ultrafast rotating speeds and mm dimensions are shown at page 3, para 35 and page 4, paras 37 and 38.

With regard to claims 12 and 16, varied types of solute materials are disclosed at page 3, para 21 and page 8, para 66.

With regard to claims 14 and 15, emulsions and suspensions are indicated on pages 7-8 in para 64.

With regard to claim 16, particles comprising coated cores are disclosed at para 19.

With regard to claim 17 see para 68 discussing particles in the nm size range.

With regard to claim 18, rotor operation process controls are disclosed in paras 40 and 49.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al PG PUBS Document US2003/0066800 in view of Holl et al and Zhou et al. Saim et al disclose production of particles by mixing solvent and supercritical fluid (page 3, para. 25) in a chamber having rotating mixing means (page 8, para. 89 and page 9, para. 90) and collecting precipitated particles (page 8, para. 91).

The claims differ in requiring the rotating mixing means to comprise a rotor. Holl et al teach such rotor to mix any combination of liquids and solids (column 3, line 27- column 4, line 20) while Zhou et al teach use of a rotor and stator to mix solutions and

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liquids to produce microparticles or nanoparticles (page 2, para. 27 and page 3, para 34.). It would have been obvious to one of ordinary skill in the art to have modified the Saim et al process, by employing a rotor containing stator vessel as the mixing means, as suggested by Holl et al and Zhou et al, in order to produce particles of well controlled and narrowly distributed particle diameter range and so as to efficiently mix with shorter mixing times required and with less back-mixing.

For claims 2-6, Holl et al also teach a shear mixing as in claim 2 (column 11, lines 59-62, multiple ports as in claim 3 (ports 14), a smooth drum rotor as in claim 4, the recited rotor speeds as in claim 5 (column 4, line 8) and the recited rotor/vessel wall spacing as in claim 6 (column 4, lines 28-34).

For claims 7-11, Zhou et al further teach any number of additional inlets for additional solvents mixed (page 4, para. 41 and figures 3-5b).

For claims 12,13,16,17 and 19, Saim et al further disclose varied types of produced particles (page 9, para. 100), use of CO<sub>2</sub> gas (para. 49), particles with cores (paragraphs 27 and 29), and uniform particle size.

For claims 14 and 15, see Holl et al at column 7, lines 58-60 and column 8, lines 6-9 inferring emulsions or suspensions and see Saim et al at paragraph 75.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pesiri et al PG PUBS document US2004/031154 concerning mixing of compressed gas and solutions to produce microparticles using varied mixing means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

July 28, 2004

  
JOSEPH DRODGE  
PRIMARY EXAMINER